REMARKS

Reconsideration and withdrawal of the rejections of the application is respectfully requested in view of the remarks and amendments herein. The Examiner is thanked for the many courtesies extended during the December 20, 2005 telephone conversation with Angela Collison, and for withdrawing the previous rejections under 35 U.S.C. §112.

THE ART REJECTIONS ARE OVERCOME

Claims 21, 24 and 25 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Wardley et al. (WO 95/30019). Claims 22, 23 and 25 were also rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Wardley as applied to claims 21, 24 and 25 above, and further in view of Mazzara et al. (U.S. Patent 5,804,196). The rejections are respectfully traversed and will be addressed collectively.

The present invention relates to methods of inducing in a feline host an immunological response against feline immunodeficiency virus comprising administering to the feline host at least one plasmid wherein the plasmid contains, and expresses *in vivo* in a feline host cell, nucleic acid molecule(s) having sequence(s) encoding feline immunodeficiency virus env protein, or gag protein, or pro protein, or gag and pro proteins, or env and gag and pro proteins.

It is respectfully asserted that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.,* 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller,* 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Turning to obviousness, it is also respectfully asserted that it is well-settled that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine,* 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir.

1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, **both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure**. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

Against this background, Wardley does not anticipate the instant invention. Nor does Wardley, when combined with Mazzara, render the instant invention unpatentable under Section 103.

Again, the present invention relates to methods of inducing in a feline host an immunological response against feline immunodeficiency virus comprising, *inter alia*, administering to the feline host at least one plasmid, which plasmid contains, **and expresses *in vivo* in a feline host cell**, nucleic acid molecule(s) having sequence(s) encoding feline immunodeficiency virus env protein, or gag protein, or pro protein, or gag and pro proteins, or env and gag and pro proteins.

The Office Action states that due to the use of the term "comprising" in the claims, the claims are interpreted to read "on the administration of a plasmid in addition to anything else." Office Action at 3-4. As "Wardley administers a plasmid in a vector", the Office Action maintains that the present claims read on Wardley because the claims do not specify that the "plasmid is naked." Office Action at 4. Applicants respectfully disagree.

Initially, it is readily apparent from the specification that the methods of the present invention only contemplate the administration of a naked plasmid-no where in the specification is mention made of inserting the plasmid into a vector prior to administration-and certainly the specification itself calls for the use of "naked plasmids" that are formulated with "physiological saline (0.9 NaCl), ultrapure water, TE buffer and the like." Specification at page 4, lines 14-17. Indeed, Example 20 clearly provides for the production and purification of the plasmids, including their resuspension in ultrapure water or in TE buffer. Example 21, entitled "Manufacture of the Associated Vaccines" calls for the mixture of plasmids in their concentrated forms and then adjusting the final concentration of the plasmids. Nowhere in the descriptions of the manufacture of the vaccines is it described that the plasmid should first be integrated into a vector such that the vaccine would then contain a vector having therein a plasmid.

Furthermore, the present claims specifically require that the administered plasmid contains, **and expresses *in vivo* in a feline host cell**, nucleic acid molecule(s). Nowhere in Wardley is there any teaching as to the administration of a plasmid in any form such that the plasmid contains, **and expresses in vivo in a feline host cell**, nucleic acid molecules.

In contrast, Wardley relates to vaccines containing DNA sequences encoding FIV gag protein and FIV env protein, wherein the DNA sequences are **contained and expressed by an expression system**, not wherein the sequences are **expressed in vivo in a feline host cell**. Wardley only relates to viral vectors or subunit vaccines. Wardley prepares plasmids that are used for expression by *E. coli* or are used to transfer the calicivirus gene to a viral vector (such as baculovirus or herpesvirus). There is no teaching or suggestion in Wardley of any plasmid that contains and expresses a nucleic acid molecule *in vivo* in a feline host, as in the present invention. Nowhere in Wardley is it described, taught or suggested that the DNA may be in the form of a plasmid that can be directly provided to the feline host. Rather, the only mention of plasmids found in Wardley relates to the use of plasmids in the construction of the **expression systems** that were ultimately used in the making of the vaccines. Wardley does not teach or suggest the use of the plasmid itself in the vaccine, nor would Wardley, as it relates only to viral vector or subunit vaccines, provide any suggestion of modifying the Wardley plasmids for use in the vaccines.

In contrast, the present invention relates to the administration of at least one plasmid to the feline host in order to induce the immunological response. As such methods and uses of plasmids, including the administration of plasmids which contains, **and expresses *in vivo* in a feline host cell**, nucleic acid molecule(s), are not taught or suggested by Wardley, the reference fails to include **all** of the elements of the claimed invention, and thus the rejection is improper and must be withdrawn.

Turning to the obviousness rejection, it is respectfully submitted that Mazzara fails to remedy the deficiencies of Wardley. Mazzara relates to a recombinant fowlpox **viral vector** that expresses the env, gag and pol genes of, *inter alia*, FIV. However, Mazzara does not teach or suggest the administration of at least one plasmid that contains such nucleic acid molecules. Furthermore, Mazzara fails to teach or suggest the administration of at least one plasmid that contains, **and expresses *in vivo* in a feline host cell**, nucleic acid molecule(s). Both Wardley and Mazzara only describe viral vectors or subunit vaccines. One of skill in the art would

recognize that viral vectors are quite different from plasmids, and neither Wardley or Mazzara, alone or in combination, would provide the skilled artisan with any suggestion or motivation to modify Wardley or Mazzara to use plasmids in the vaccines, let alone plasmids that contain, **and express *in vivo* in a feline host cell**, nucleic acid molecule(s). Accordingly, the combination of Wardley and Mazzara is still insufficient to render the present invention obvious as neither Wardley nor Mazzara, either alone or in combination, would provide one of skill in the art with the incentive and expectation of success to administer at least one plasmid that contains, **and expresses *in vivo* in a feline host cell**, nucleic acid molecule(s), to induce an immunological response in a host feline. Therefore, the obviousness rejection is also improper and should be withdrawn.

Consequently, reconsideration and withdrawal of the rejections under 35 U.S.C. §§ 102(b) and 103(a) is respectfully requested in view of the remarks and amendments herein.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, an interview with the Examiner is respectfully requested, prior to issuance of any paper other than a Notice of Allowance; and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the remarks herewith and those of record, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance, or an interview at a very early date with a view to placing the application in condition for allowance, are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully Submitted,

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